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| APPLICATION NO.                   | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO |  |
|-----------------------------------|---------------|----------------------|-------------------------|-----------------|--|
| 09/127,059                        | 07/31/1998    | AMEDEO LEONARDI      | 648/1D340-US            | 9662            |  |
| 75                                | 90 01/22/2003 |                      |                         |                 |  |
| ROBERT C SULLIVAN                 |               |                      | EXAMINER                |                 |  |
| DARBY & DARBY<br>805 THIRD AVENUE |               |                      | BERNHARDT, EMILY B      |                 |  |
| NEW YORK, N                       | IY 10022      |                      | ART UNIT                | PAPER NUMBER    |  |
|                                   |               |                      | 1624                    | 21              |  |
|                                   |               |                      | DATE MAILED: 01/22/2003 |                 |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| es.  | <b>-</b>  |                          |                 |                |  |  |  |  |  |
|--|---|--------------------------|-----------------|----------------|--|--|--|--|--|
| Advisory Action  |   | Application No.          | Applicant(s)    |                | l at al  |  |  |  |  |
|  |   | 09/127,059               | LEONARDI et al. |                |  |  |  |  |  |
|  |   | Examiner Emily Bernhardt |                 | 1624           |  |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address  |   |                          |                 |                |  |  |  |  |  |
| THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.  |   |                          |                 |                |  |  |  |  |  |
| Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.  THE PERIOD FOR REPLY [check only a) or b)]  |   |                          |                 |                |  |  |  |  |  |
| the first the section of the final rejection   |   |                          |                 |                |  |  |  |  |  |
| b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).  |   |                          |                 |                |  |  |  |  |  |
| Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                          |                 |                |  |  |  |  |  |
| 1. A Notice of Appeal was filed on 12/26/02. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.   |   |                          |                 |                |  |  |  |  |  |
| 2. X The proposed amendment(s) will not be entered because:  |   |                          |                 |                |  |  |  |  |  |
| (a) X they raise new issues that would require further consideration and/or search (see NOTE below);   |   |                          |                 |                |  |  |  |  |  |
| (b) ☐ they raise the issue of new matter (see NOTE below);   |   |                          |                 |                |  |  |  |  |  |
| (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the   |   |                          |                 |                |  |  |  |  |  |
| issues for appeal; and/or (d) $\square$ they present additional claims without canceling a corresponding number of finally rejected claims.  |   |                          |                 |                |  |  |  |  |  |
| NOTE: See attached response.   |   |                          |                 |                |  |  |  |  |  |
|  |   |                          |                 |                |  |  |  |  |  |
| 3. 🗆 🔏   | Applicant's reply has overcome the following rejec  | etion(s):                |                 | <u></u>        |  |  |  |  |  |
| -<br>4.□ I   | Newly proposed or amended claim(s)a separate, timely filed amendment canceling the i  | non-allowable claim(s    | w               | ould be allowa | able if submitted in                                 |  |  |  |  |
| 5. 🗆 -   | The a) $\square$ affidavit, b) $\square$ exhibit, or c) $\square$ reques application in condition for allowance because:  | t for reconsideration    | has been co     | onsidered but  | does NOT place the                                   |  |  |  |  |
|  | The affidavit or exhibit will NOT be considered bed<br>by the Examiner in the final rejection.  |                          |                 |                |  |  |  |  |  |
| 7. 🖾 1   | For purposes of Appeal, the proposed amendment(s) a) $\boxtimes$ will not be entered or b) $\square$ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. |                          |                 |                |  |  |  |  |  |
|  | The status of the claim(s) is (or will be) as follows:  |                          |                 |                |  |  |  |  |  |
|  | Claim(s) allowed: 21  |                          |                 |                |  |  |  |  |  |
|  | Claim(s) objected to: <i>3, 19, and 20</i> Claim(s) rejected: <i>1, 2, 4, and 5</i>   |                          |                 |                |  |  |  |  |  |
|  | Claim(s) withdrawn from consideration:  |                          |                 |                |  |  |  |  |  |
| 8. 🗆   | The proposed drawing correction filed on  | is a) 🗆                  | approved or     | r b) 🗆 disappr | oved by the Examiner.                                |  |  |  |  |
|  | Note the attached Information Disclosure Stateme  |                          |                 |                | ~  |  |  |  |  |
| 10. 🗆 O  |   |                          | • •             |                | EMILY BERNHARDT<br>PRIMARY EXAMINER<br>ART UNIT 1624 |  |  |  |  |

Application/Control Number: 09/127059

Art Unit: 1624

The after final response raises more issues for consideration. The scope of bicyclic aryl appears to be limited to naphthyl in the "B" definition but wording that precedes this moiety includes 9-membered rings thus obscuring applicants' intent. Also "B" is now depicted as a substituent on the phenyl ring whereas originally it is directly attached to the piperazine ring and so lacks antecedent basis in the specification. Additionally, the scope of fused-B hetero rings now recited would necessitate a reinstatement of par.one rejection made in earlier actions regarding scope for "how to use and would still lack descriptive support for the following reasons. The hetero ring scope is broader than the original proviso (1) as stated in the specification on p.3 for "heteroaryls" and the instant claim language includes not

only heteroaromatics but saturated,non-aromatics as well. Also the optional substitution for these rings is not seen anywhere in the original dsiclosure. The substituents listed on p.5 of the specification are described as being for "aryl" groups. Defining B to be either phenyl or naphthyl optionally substituted with monovalent substituents as listed in main claim 1 or (b) phenyl which is fused to form benzodioxanyl or (c) represents phenyl ring which is fused to form indolyl would overcome new matter and scope of claim issues.

Application/Control Number: 09/127059

Page 3

Art Unit: 1624

Even if the above 112 issues were not present, the narrower genus now presented for main claim 1 would require additional consideration and search for additional art as to patentability of claims previously rejected over Janssen. The newly added proviso (to remove Janssen) raises another issue for descriptive support. Note support for the claims depends on the disclosure as filed and not on the prior art. With regard to the rejection over Shiota, it would still remain, as the English translation of foreign priority document is incomplete as no structural formulas are present. Assuming the same formula is present in foreign application as claimed herein, Shiota otherwise describes the same moieties as claimed herein but the new matter problems present in the instant claims would **not** entitle applicants to

119 benefit as compliance with 35 USC 112 has not been met. Note In re Gostelli 10 USPQ 2d 1614; Kawai v. Metlesics 178 USPQ 158 which are on point.

A timely filed amendment presenting only allowable subject matter (i.e. claims 3 and 19-21) would be entered.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

Application/Control Number: 09/127059

Page 4

Art Unit: 1624

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

FBeinhaudt
EMILY BERNHARDT

**PRIMARY EXAMINER** 

**GROUP 1600** 

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